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EXAMINER	
LEVKOVICH, NATALIA A	

ART UNIT	PAPER NUMBER
1797	

NOTIFICATION DATE	DELIVERY MODE
09/17/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/089,136	HEIMBERG ET AL.	
	Examiner	Art Unit	
	NATALIA LEVKOVICH	1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 June 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *19,21,23,25,27,35,37,41,43,49 and 53-56* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *19,21,23,25,27,35,37,41,43,49 and 53-56* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

1. Applicant's amendments and remarks filed 06/04/2009 have been acknowledged.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

Drawings

3. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims, as well as any structural detail that is essential for a proper understanding of the disclosed invention. Therefore, the temperature sensors operatively connected to the control unit of claim 19 and assigned to each segment, as is currently recited in the amended claim 41, as well as the two control units configured to actuate the same two or more devices for heating and cooling (see the amended claims 19 and 56), must be clearly shown and referenced, or the feature(s) canceled from the claim(s). No new matter should be entered.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claim 56 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The amended claim 56 recites an additional control unit configured for actuating the two or more devices for heating and cooling. Upon further reviewing the original specification, Examiner found no support for this limitation. 'The specification supports the Peltier elements 7 ['devices for heating and cooling'] being connected electrically to a first control unit 13; while a second control unit 15 is configured for actuating the heat exchangers 6. The specification does not describe both control units being connected to Peltier elements 7 ['devices for heating and cooling'].

6. Claims 19, 21, 23, 25, 27, 35, 37, 41, 43, 49 and 53-56 remain rejected under 35 U.S.C. 112, second paragraph, as being unclear for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Referring to claim 19 which recites a control unit for "actuating the system, wherein the devices are actuated independently of one another to set and maintain different temperatures in two adjacent segments, it remains unclear whether or not the heating and cooling devices are intended to be connected to

the control unit and to temperature sensors, such connections and sensors would be necessary for providing a feedback required for implementation of the control. Additionally, it remains unclear how the PCR parameter optimization can be carried out without any means for measuring at least one result variable needed as a criterion for such optimization. Therefore, the claim is incomplete for omitting essential elements, such omission amounting to a gap between the elements. See MPEP § 2172.01. See also claim 49 regarding a means for setting the predetermined temperature difference, as discussed previously.

Claim Rejections - 35 USC § 103

7. Claims 19, 21, 23, 25, 27, 35, 37, 41, 43, 49 and 53-56 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gordon et al. (US 5601141) in view of Potter et al. (US 5819842).

With respect too claims 19, 21, 35, 37 and 41, Gordon discloses a modular thermal cycler that carries samples through one or more predetermined temperature profiles and comprises a base with an array of modules ['segments'] mounted on the base. The modules are "substantially isolated from one another, thermally and functionally", each module including a temperature sensor "adjacent the samples, an electrical resistance heating element, and a circulating fluid heat exchanger for step cooling...The modules are preferably formed in three layers--a sample plate ['thin-walled reaction vessel holders'- see element 14a of Figure 4], a heater plate, and a cooling plate ['physically distinct devices

for heating and cooling', see elements 14 b-c of Figure 4] adjacent to a manifold… The sample plate is preferably replaceably secured at the upper surface of the module on the heating plate… The sample plate is adapted to receive a *standard micro-titration plate*, or other labware, in a close, heat-transmitting engagement. The heater plate and cooling plate may be formed integrally"- (Abstract; Col.1, line 5; Col.2, lines 10-40). Gordon also teaches that the thermal cycler includes a controller which "regulates the electrical current and cooling fluid flows to each module in response to a signal from a temperature sensing element associated with each module"(Col.2, lines 15-20; Col.4, line 45; Col.5, line 55). Thus, the multiple modules ['segments'] of Gordon are configured to control sample temperatures in multiple standard micro-titter plates independently.

Although Gordon does not explicitly describe an embodiment with the segments of the micro titer plate receiving element being sized to receive a single standard micro-titter plate for independently controlling corresponding portions of the micro-titter plate, Gordon, however, does teach that "In biological and chemical testing and experiments it is often necessary to repeatedly cycle samples of a biological specimen or chemical solution through a series of different temperatures where they are maintained at different set temperatures for predetermined periods of time .... Modern biological testing often uses micro-titration plates. A standard such plate is a plastic sheet with 96 depressions, each adapted to hold one of the samples to be processed" (Col.1, lines 9-19). Gordon also teaches that cycling the samples in groups, independently of one another,

can be organized both "as a single module or zone or as groups of modules or zones"(see Col.2, lines 55-59).

Potter et al. disclose a device for independent temperature control of multiple samples disposed in different portions of a single micro-titter plate (see Abstract). The device comprises, as shown in Figures 1-3, a standard micro-titer plate 10 with wells 13, the temperature within each well being independently controlled by physically distinct segments 21 of sample vessel receiving structure 20, the segments being aligned with respective physically distinct temperature controlling elements 22. Potter also discloses Peltier thermoelectric devices (very well known in the art as devices for providing both heating and / or cooling) as possible embodiments for the elements 22 (see Col.2, line 43). It would have been within the ordinary skill of an artisan at the time the invention was made to have modified the apparatus of Gordon such as to configure the independently controlled modules / sections for individual and independent heating / cooling of separate portions of a single standard micro-titer plate, in order to allow separate temperature control for some of the samples of the micro-titer plate (particularly when a single module thermal cycler is employed as an option, as taught by Gordon), which would also broaden the scope of applicability of the apparatus, as well as would further enhance its commercial / marketing value.

As to the reaction vessels of the standard micro-titer plate containing a same reaction mixture, as recited in the instant claims, the disclosure of Gordon does not specifically describe this feature. Nevertheless, it would have been clearly within the ordinary skill of an artisan at the time the invention was made to have

filled the wells of the micro-titer plates in the modified apparatus of Gordon either with different reaction mixtures, or , alternatively (depending on particular goals of testing), with the same reaction mixture, the latter may be useful, for example, when a bigger volume of a product is desired.

Referring to claim 21, the base can be "changed easily to accommodate different sample holders adapted to different labware, or to hold samples directly" (Col.4, line 20). In particular, Figure 4 shows micro-titration plate P disposed over plate 14a ['reaction vessel receiving element'] having a base forming one piece with a plurality of wells ['tubular, thin-walled reaction vessel holders'].

With respect to claims 23 and 25, Gordon teaches that "the modules are spaced laterally, from one another which in combination with forming the base of the insulator, provides a good degree of thermal isolation of each module" (Col.3, lines 40-45). It would have been also within the ordinary skill of an artisan at the time the invention was made to have modified the thermal conductivity of the gaps (depending on particular goals of thermo-cycling) by filling them with materials having different thermal conductivity characteristics (including thermal insulators), in order to provide flexible and precise temperature control in the modified apparatus of Gordon.

Regarding claim 27, Gordon refers to the use of Peltier elements for heating or cooling as being well known in the art in column 1, lines 30-35.

Regarding claim 43, Figure 6 shows channel temperature equalization element 46 filled with a heat dissipating fluid.

With respect to claims 49, and 53-55 which recite limitations to the process of using the device, these limitations are not attributed patentable weight in a claim to an apparatus. Additionally, it appears that the apparatus of Gordon et al. is capable of operating in the recited manner. Gordon modified by Potter would have suggested a segmented receiving element capable of being independently heated / cooled, i.e., a structure capable of maintaining a predetermined temperature difference between adjacent segments and, hence, capable of being used for optimizing temperature related process parameters.

As to claim 56, Gordon discloses possible use of multiple controllers (as a less preferred embodiment) in Col. 2, lines 17 plus.

Double Patenting

8. Claims 19, 21, 23, 27, 35, 37, 41, 49 and 56 remain provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-2 of co-pending application 11/470463, claims 1-2 of co-pending application 11/850345, and claim 18 of co-pending application 11/651986. Although the conflicting claims are not identical, they are not patentably distinct from each other because all the elements recited in the instant claims are fully within the scope of the above listed claims of the co-pending applications . See the appropriate paragraphs of the 06/12/2008 Office Action.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Response to Arguments

9. Applicant' s arguments filed 06/04/2009 have been fully considered but they are not persuasive, or moot in view of new grounds of rejection.

Applicant argues that "Gordon et al. teaches away from a reaction vessel receiving, element physically divided into two or more segments that are thermally insulated from one another in combination with a standard micro-titer plate spanning an entirety of the reaction vessel receiving element" because "Gordon et al. states that prior devices "operate on only one plate" and the problem of expanding those devices to handle multiple plates". Examiner disagrees. First, Gordon does teach a reaction vessel receiving, element physically divided into multiple segments configured to support a plurality of standard micro-titer plates (see Figure 1 and the art discussion above).). It would have been also within the ordinary skill of an artisan at the time the invention was made to have modified the apparatus of Gordon such as to configure the independently controlled segments for individual and independent heating / cooling of separate portions of a single standard micro-titer plate, in order to allow separate temperature control for some of the samples of the micro-titer plate, such control would further broaden the scope of applicability of the apparatus, thus enhancing its commercial value. Second, Gordon does teach embodiments which may include only one plate: "while the invention has been described with respect to a cycler with multiple modules, the fast response temperature control of the present invention can be used even in a single module

cycler (Col.2, lines 55-59). Additionally, disclosed examples and preferred embodiments do not constitute a teaching away from a broader disclosure or non-preferred embodiments. *In re Susi*, 440 F.2d 442, 169 USPQ 423 (CCPA 1971). Thus, modifying the apparatus of Gordon by providing a single standard micro-titer plate spanning over the plural modules [segments'] of Gordon would be in accord with the disclosure of the patent and obvious to one having ordinary skills of the art.

Applicant requests further clarification to the previous statement of the Office "that Gordon et al. teaches that "cycling the samples in groups, independently of one another, can be organized both 'as a single module or zone or as groups of modules or zones". In response, Examiner would like to draw Applicant's attention to Col.2, lines 55-59, teaching that: "while the invention has been described with respect to a cycler with multiple modules, the fast response temperature control of the present invention can be used even in a single module cycler"; to Col.8, lines 45-48, teaching that "viewed as a method, the invention includes cycling the samples in groups (organized as a single module or zone or as groups of modules or zones) substantially independently of one another'; as well as to pages 6 plus of the BPA Decision of 01/24/2008.

Applicant also argues that "Potter et al. also teaches away from a reaction vessel receiving element physically divided into two or more segments that are thermally insulated from one another in combination with a standard microtiter plate spanning an entirety of the reaction vessel receiving element" because "Potter et al. teaches that the thermal mass of the temperature controlled

components should be kept to a minimum", while "Gordon et al. teaches the processing of large numbers of biological or chemical samples". Examiner notes that Potter was cited to support the concept of modular temperature control within a single plate, which Potter does teach (see the art rejection above).

Applicant further argues that Potter "fails to disclose two or more physically distinct devices for heating and cooling the reaction vessel receiving element, wherein each device for heating and cooling is aligned with and dedicated to heat and cool only one segment such that each segment is aligned with a device for heating and cooling. Instead, the heater element 22 of Potter et al. is embedded in a matrix 24 which is in turn seated on a cooling arrangement 25/26/27, which cooling arrangement clearly spans the entire unit and thus all heater elements 22 in FIG. 2 thereof. Therefore, Potter et al. fails to teach two or more physically distinct devices for heating and cooling the reaction vessel receiving element, wherein each device for heating and cooling is aligned with and dedicated to heat and cool only one segment such that each segment is aligned with a device for heating and cooling". Examiner disagrees. As was shown above, Potter discloses a device for independent temperature control of multiple samples disposed in different portions of a single standard micro-titter plate. The device includes, as seen in Figure 2, physically distinct segments 21 aligned with respective [dedicated'] physically distinct temperature controlling elements 22, which may be Peltier thermoelectric devices ['physically distinct devices for heating and cooling']. The fact that the devices are supported by common matrix 24, does not preclude the respective segments 21 and elements

22 from being physically distinct and aligned with each other in one-to-one fashion. Additionally, each element 22 is thermally isolated from the supporting matrix by discs 23 having high thermal resistance. Thus, Potter et al. does teach a plurality of physically distinct devices for heating and cooling the reaction vessel receiving element, each device for heating and cooling being aligned with and dedicated to only one segment; and each segment being aligned with a respective device for heating and cooling. Examiner also notes that the instant claims do not require absolute thermal insulation between the segments and respective elements, notwithstanding the fact that such insulation would be simply impossible.

Applicant further argues that "Gordon et al. also fail to teach or suggest two or more physically distinct devices for heating and cooling the reaction vessel receiving element, wherein each device for heating and cooling is aligned with and dedicated to heat and cool only one segment such that each segment is aligned with a device for heating and cooling. Instead, a cooling member 18 spans an entire row of modules 14 and is, therefore, neither aligned with nor dedicated to only one module". Based on this argument, Applicant concludes that "the *cooling device of Potter et al. is essentially the same as that of Gordon et al.* and fails to modify Gordon et al". Examiner notes that elements 18 (see Figure 2) are not the devices for heating and cooling the Office is referring to in the art rejections. Elements 18 are electrical conduits which carry electrical power to the modules designed to protect the electrical conductors inside from a short circuit due to an inflow of water (Col.3, lines 60 plus). Figures

1, 2 and 4 show a plurality of physically distinct segments 14-a aligned with respective ['dedicated'] physically distinct elements 14 b-c ['devices for heating and cooling'] in one-to-one manner. Additionally, as noted above, the instant claims do not require absolute thermal insulation between the segments and respective elements, such insulation being not possible.

Conclusion

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Natalia Levkovich whose telephone number is 571-272-2462.

The examiner can normally be reached on Mon-Fri, 2 p.m.-10 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Jill Warden/
Supervisory Patent Examiner, Art Unit 1797